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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,514	09/14/2001	Takeya Abe	018793-253	4410
7590	05/02/2007		EXAMINER	
Robert G Mukai Burns Doane Swecker & Mathis PO Box 1404 Alexandria, VA 22313-1404			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	
			MAIL DATE	DELIVERY MODE
			05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/936,514	ABE ET AL.
	Examiner	Art Unit
	Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,9,11-16 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,9,11-16 and 25-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/27/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

1. Claims 1, 3, 9, 11-16, and 25-31 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3, 9, 11-16, and 25-31 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The arguments filed 02/12/2007 have been fully considered but they are not persuasive for the reasons of record as further explained.

The method steps reciting the products must comply with the written description requirement. As stated previously, the amended claims are genus claims directed toward a method using a genus of nitrile hydratase of any amino acid sequence and structure from any microorganism fungus body although the claims have been amended to include the limitation "for removing a protein". The scope of the claims includes many microorganisms and many nitrile hydratase enzymes with widely differing structural, chemical, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

As stated in the previous Office Actions recitation of the name "nitrile hydratase" and its source as a microorganism fungus body do not define any structural features and amino acid sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features and amino acid sequences commonly possessed by the genus. As stated in the previous Office Action, the specification discloses a MT-10827 (FERM BP-5785) which is not a not a fungus, but is instead an *E.coli* host cell transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352), and its use in converting acylonitrite to its corresponding amide acrylamide.

However, the specification does not provide an amino acid sequence of the said bacterial

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nitrile hydratase from *Pseudonocardia thermophila* JCM3095, and fails to provide a written description of additional nitrile hydratase enzymes and microorganisms as encompassed by the claimed genus in the amended claims. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the claimed genus.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of nitrile hydratase of any amino acid sequence and structure from any microorganism fungus body

Amending the claims to recite the *E.coli* host cell MT-10827 (FERM BP-5785) transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352) may overcome the rejection.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, 9, 11-16, 25-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oriel et al. (WO 99/55719; reference of record) in view of Chen. (J Biol Chem. 1967 Jan 25;242(2):173-81; reference of record). The reference teachings have been stated in the previous Office Actions.

Applicants' arguments filed 02/12/2007 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the process of Oriel et al. such that the amide solution is subjected to acid-charcoal treatment as taught by Chen as stated in the previous Office Actions for the purposes of

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having a simple and beneficial purification process that produces an amide compound and removes impurities. This is within the level of ordinary skill at the time the claimed invention was made. The examiner takes the position that the modified process of Oriel et al. would inherently remove impurities including proteins since the process involves not only contacting the solution with activated carbon but also includes steps for concentrating or precipitating by distillation or evaporation the amide solution, thereby removing contaminating proteins.

The examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the amended claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

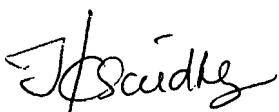
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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER